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10/099,772	03/15/2002	Gary L. Long	END-838	4856

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EXAMINER

VRETTAKOS, PETER J

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/099,772

Applicant(s)

LONG ET AL.

Examiner

Peter J Vrettakos

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1-10-05.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23,25-27,29 and 30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23,25-27,29 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The instant action is final. Changes to rejections are made in bold.

Claims 1-23, 25-27, and 29-30 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 30 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner cannot locate in the Specification a means to support a relatively rigid member for rotation...as written into claim 30.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 13-18, 20-22, 25-27, and 29 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Komiya ('624).

Independent claims 1, 14, 20, 29, respectively

Komiya discloses a method of treating tissue within a patient, said method comprising the steps of:

providing at least one instrument (catheter 5 which can envelop element 10; **5 AND 10 comprise the “instrument” – this rationale is further elaborated in the Response to Arguments section, *infra***; col. 3:32-35;) having a distal end; **the instrument (5 and 10) adapted to grasp or cut tissue – see figure 6**);

providing at least one channel (3) for accessing a treatment site;

extending at least a portion of the instrument from a distal end of the channel to access the treatment site (see figure 6); and

constraining motion (using instrument element 6 in figure 6) of the distal end of the instrument (catheter 5 which can envelop element 10; col. 3:32-35) along a predetermined path (as determined by instrument element 6) at the treatment site; and

grasping or cutting tissue with the instrument (5 and 10; see figure 6)

Komiya discloses a method of treating tissue within a patient, said method comprising the steps of:

providing a first instrument (catheter 5 which can envelop element 10; col. 3:32-35) having a distal end, **wherein the first instrument (5 and 10) is adapted to cut or grasp tissue (see figure 6);**

providing a second instrument (6) having a distal end;

providing a first channel (3) for accessing a treatment site;

providing a second channel (4) for accessing a treatment site;

advancing the first instrument (catheter 5 which can envelop element 10; col. 3:32-35) from a distal end of the first channel to a treatment site within the patient (see figure 6);

advancing the second instrument from a distal end of the second channel (4) to the treatment site (*in the direction of the treatment site*, see figure 6);

and cooperating motion of the distal ends of the first (catheter 5 which can envelop element 10; col. 3:32-35) and second (6) instruments such that the distal ends follow a predetermined path (see figure 6).

Komiya discloses a method of treating tissue within a patient, said method comprising the steps of:

providing an endoscope having at least one instrument channel (3);

disposing the endoscope in a body lumen (8);

advancing a flexible instrument **for grasping or cutting tissue (5 and 10; see figure 6)** (catheter 5 which can envelop element 10; col. 3:32-35) from the distal

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end of the instrument channel to access a treatment site in the body lumen (see figure 6); and

constraining motion (using instrument element 6 in figure 6) of the distal end of the flexible instrument (catheter 5 which can envelop element 10; col. 3:32-35) along a desired path (90 degree angle with respect to the endoscope 1 shown in figure 6) as the instrument is advanced from the distal end of the instrument channel; **and cutting or grasping tissue with the flexible instrument (5 and 10; see figure 6).**

Komiya discloses a method of treating tissue within a patient, said method comprising:

disposing a relatively rigid member (see figure 3 where 5 bends and 6 stays relatively straight) (6) for guiding motion of a medical instrument (catheter 5 which can envelop element 10; col. 3:32-35) at the distal end of an endoscope (1);

inserting a **relatively flexible (see figure 6 as element 5 curves 90 degrees)** instrument (catheter 5 which can envelop element 10; col. 3:32-35) having a distal end through an instrument channel (3) of said endoscope;

connecting the **relatively flexible** instrument (catheter 5 which can envelop element 10; col. 3:32-35) to the **relatively rigid member (6)**;

inserting the **relatively rigid member** and the **relatively flexible** instrument into the patient (8, figure 6); **and**

constraining motion of the distal end (end of element 5) of the relatively flexible instrument with the relatively rigid member (the attachment of 6 at the distal end of 5 restricts twisting of 5) without substantial bending of the relatively rigid member (see figure 3); wherein motion of the distal end of the relatively flexible instrument (5 and 10) is constrained along a desired path as the relatively flexible instrument is advanced from the distal end of the instrument channel (see figures 2 and 3).

Note: the reader is directed to the Applicant's figures 7-16 to appreciate the similarities to Komiya's invention in figures 3,6, and 12.

Dependent claims (Examiner's comments directed toward Komiya)

2. The method of Claim 1 wherein the step of constraining motion of the distal end of the instrument comprises restricting twisting of the instrument (catheter 5 which can envelop element 10; col. 3:32-35) about the longitudinal axis of the instrument (see figure 3, element 6 is attached at one point of element 5, thereby restricting twisting).
3. The method of Claim 1 wherein the step of constraining motion of the end of the instrument comprises bending the instrument (see figure 6, elements 5,6, and 10).
4. The method of Claim 3 wherein the step of bending the instrument comprises

bending the instrument through an angle of at least about 90 degrees (element 5, figure 6).

5. The method of Claim 1 wherein the path is not parallel to a longitudinal axis of the channel (see figure 6 – the path is at a right angle or 90 degrees to the channel longitudinal axis).

6. The method of Claim 1 wherein the step of constraining motion of the end of the instrument comprises constraining motion of the end of the instrument along an arc (the arc is depicted in element 5 in which instrument 10 rests in figure 6).

7. The method of Claim 1 wherein the step of providing at least one channel comprises providing a channel having a proximal channel opening (inherent) outside the patient and a distal channel (shown in figure 3) opening within the patient.

8. The method of Claim 1 wherein the step of constraining motion of the end of the instrument comprises bending the instrument (catheter 5 which can envelop element 10; col. 3:32-35) to position the end of the instrument adjacent a lumen wall (8, see figure 6).

13. The method of Claim 1 wherein the first instrument comprises a hollow member,

and wherein the method further comprises communicating a source of vacuum with the hollow member ("suction", col. 3:25-28).

15. The method of Claim 14 wherein the step of cooperating motion of the distal ends of the first (catheter 5 which can envelop element 10; col. 3:32-35) and second instruments (6) comprises engaging the distal ends of the first and second instruments, one with the other (figure 6).

16. The method of Claim 14 wherein the step of cooperating motion of the distal ends of the first and second instruments comprises bending *of the first instrument* (see figure 6).

17. The method of Claim 14 wherein the step of cooperating motion of the distal ends of the first and second instruments comprises preventing twisting *of the first instrument* (catheter 5 which can envelop element 10; col. 3:32-35) (see figure 6).

18. The method of Claim 14 wherein the step of cooperating motion of the distal ends of the first and second instruments comprises bending *the first instrument* through an angle of about 90 degrees (see figure 6).

21. The method of Claim 20 wherein the step of constraining motion of the end of the flexible instrument comprises bending the instrument (catheter 5 which can envelop

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element 10; col. 3:32-35) as the instrument is advanced from the instrument channel (see figures 2 and 3).

22. The method of Claim 20 wherein the step of bending the instrument (catheter 5 which can envelop element 10; col. 3:32-35) comprises bending the instrument through an angle of at least about 90 degrees (figure 6).

25. The method of Claim 20 wherein the step of constraining motion of the end of the instrument comprises constraining motion of the end of the instrument along an arc (the arc is depicted in element 5 in figure 6).

26. The method of Claim 20 wherein **the method comprises restricting twisting (the attached element 6 restricts twisting) of the distal end of the instrument (distal end of 5) as the instrument is advanced along the desired path (this is depicted through arrows in figures 2 and 3).**

27. The method of Claim 20 wherein **the method comprises engaging tissue (see figure 6) with at least one jaw (again see figure 6) disposed at the distal end of the instrument (5 and 10), and wherein the method comprises restricting twisting of the distal end of the instrument as the instrument is advanced along the desired path (see rationale for rejection of claim 26).**

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9, 10, 11, 12, 19 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Komiya in view of Sekine et al. ('753).

9. Sekine et al. (Sekine) discloses an analogous method (with an analogous device but without an analogue to Komiya element 6) that further comprises the step of cutting a tissue sample (figure 11, col. 5:50-53; "mucous membrane"). Also note the embodiment in figure 7.

10. The method of Claim 9 further comprising the step of removing the tissue sample through the channel without removing the instrument from the channel (**Komiya** suction of viscous fluid, col. 3:25-28). Note: the Examiner contends that disclosure of "suction" is sufficient to make obvious "removing the tissue sample through the channel without removing the instrument."

11. The method of Claim 1 further comprising the step of ablating tissue (Sekine discloses a high frequency power supply in col. 5:57, which makes obvious tissue

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ablation). Also, Sekine discloses other treatment methods involving lasers and HF probes (col. 1:33-36)

12. The method of Claim 1 further comprising the step of treating the tissue with argon plasma (see col. 1:33-36).

19. and 23. The method of Claim 18 or 22 wherein the step of cooperating motion of the distal ends of the first (Komiya catheter 5 which can envelop element 10; col. 3:32-35) and second (Komiya 6) instruments comprises bending the first (Sekine 13, which is analogous to Komiya 5) through an angle of at least about 180 degrees (see Sekine figure 7).

Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Komiya in view of Sekine by including additional applications (cutting, ablating) to which the disclosed device can perform. The motivation would be to increase the number of applications of the Komiya device.

Response to Arguments

Applicant's arguments filed 1-10-05 have been fully considered but they are not persuasive. Amendments were made in the response, which have required the Examiner to change the rejection slightly. The Office contends that elements 5 and 10

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can be defined as one instrument. This is because in col. 3:32-35, Komiya mentions that element 5 can be used as a catheter. To this end, the forceps (10) in Komiya can be defined as part of catheter 5, and therefore it is proper to define elements 5 and 10 as one instrument (a catheter with forceps). This rationale is used in the rejections above.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

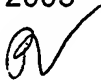
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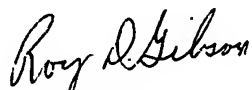
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J Vrettakos whose telephone number is 703 605 0215. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C Dvorak can be reached on 703 308 0994. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pete Vrettakos
April 4, 2005




ROY D. GIBSON
PRIMARY EXAMINER